Coming up with a COVID (cure?):
Using e-consent and national recruitment in a fully-remote clinical trial

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Introduction:
The STOP COVID Trials were innovative fully-remote randomized controlled trials of fluvoxamine (a sigma1 receptor agonist with anti-inflammatory properties) vs placebo for treatment of outpatients with early COVID-19 who were self-isolating at home.

Methods:
The trials used eConsent and an electronic data capture system with integrated recruitment from the EPIC electronic health record system. The trials reduced participant burden and prevented spread of infection by allowing patients to participate from home. The trials also ensured equity in research participation by encouraging participation of individuals from racial and ethnic groups that are disproportionately affected by severe COVID-19.

Results:
STOP COVID 1 screened 1337 individuals, randomized 181, and included 152 in the main analysis, including 25% black participants. STOP COVID 2 screened 2475, randomized 670, and included 547 in the main analysis, including 13% Hispanic participants. Enrollment for STOP COVID 2 ended early due to low event rates and difficult recruitment after COVID-19 vaccine rollout, but is still adequately powered for some important secondary and long-term follow up analyses.

Conclusions:
It is possible to recruit a diverse sample for participation in a fully-remote clinical trial during a pandemic.

References:

For more information about the STOP COVID Trials, go to healthymind.wustl.edu